REMARKS

The Office Action of January 28, 2010 and the references cited therein have been carefully studied. Favorable reconsideration and allowance of the claims are respectfully requested.

I. Claim Status and Amendments

Claims 4-8, 11, 20, 22, 24-27, and 31-36 presently appear in this case.

Claims 11, 20, and 22 have been withdrawn from consideration.

Claims 4-8, 24-27, and 31-36 stand rejected. No claims have been allowed.

By way of the present amendment, claim 31 has been amended to specify that " the method is performed so as to crosslink the hyaluronic acid derivative during concentration and drying." Support for this amendment can be found in the disclosure, for example, at paragraph [0056] on page 28 of the original specification, which corresponds to paragraph [0106] of US 2007/0134334 Al.

In addition, claim 7 has been amended to insert "the" before "microparticles" to conform to US practice of antecedent basis to thereby conform with the recitation in claim 26.

No new matter has been added.

II. Obviousness Rejection

Claims 4-8, 23-27, and 31-36 have again been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto et al. (US Patent Application Publication 2003/0211166, published 13 Nov 2003) in view of Schense et al. (US Patent Application Publication 2003/0012818, 16 Jan 2003) and Shu et al. (Biomacromolecules, 2002, 2, pps. 1304-1311) for the reasons set forth on pages 4-11 of the Office Action. The rejection is respectfully traversed. The arguments set forth in the response filed October 28, 2009 traversing this rejection are reiterated herein by reference.

As previously argued in the October 28, 2009 response, the rejection seems to be the result of a misunderstanding of the disclosure of main reference to Yamamoto et al. In this regard, the examiner has stated that "Yamamoto et al. teaches the method wherein said dilute solution contains the crosslinking agent prior to dispersing the solution by spraying (page 4, paragraph 43 and 44)." Applicants again respectfully disagree and submit that Yamamoto et al. fails to disclose or suggest that for which it is being offered.

Instead, at page 4, paragraph [0043], Yamamoto et al. actually discloses:

> The solution was treated with EDC in an aqueous phase concentration of 50 milliMolar (mM) for a period of 24 hours. The EDC treatment of the HA solution formed cross-links and thereby Increased the molecular weight of the HA and enhanced its film forming properties.

Yamamoto et al. clearly discloses that crosslinks on HA were formed by treating the HA solution with EDC for a period of 24 hours. The solution of crosslinked HA was used for preparing microspheres (see page 4, paragraph [00441] of Yamamoto et al.).

By contrast, the method of independent claim 31 of the present application comprises steps b) and c), which call for dispersing the solution by spraying to form microparticulate droplets, and concentrating the solution contained in the droplets to facilitate crosslinking. Thus, in the claimed method, the crosslinking reaction of the polysaccharide derivative occurs in the microparticulate droplets produced by spraying of the reaction solution during forming of the microspheres, as was argued in the last response. This key technical feature of the claimed method is neither shown nor made obvious by either Yamamoto et al. alone or in combination with any of the secondary references of Schense et al. of Shu et al. As none of references show or make obvious this feature, no combination of the references

together, even if such a combination were obvious, could reach the subject matter of main claim 31.

Instead, Yamamoto et al. discloses crosslinking agent co-formulated into microspheres or a microsphere formed with crosslinked hyaluronic acid. Thus, even in light of this disclosure in Yamamoto et al. referred to in the Office Action, the above-noted feature of the claimed method is neither shown nor made obvious by Yamamoto et al. Nor is it may obvious by any combination of Yamamoto et al., Schense et al. and Shu et al.

Yet in the present Office Action, the examiner (at page 8, line 15 to page 9, line 2) states as follows:

> Applicant emphasizes that in the instant invention the crosslinking reaction occurs in the microparticulate droplets produced by spraying of the reaction solution. In acknowledgement of Applicant's description of what is asserted to be a key technical feature of the claimed method, the instant specification at paragraph 20 spanning pages 10-11 describes embodiments of the method wherein the crosslinking is performed during concentration or in parallel with drying, and at page 20, paragraph 56 wherein the method is performed so as to crosslink the hyaluronic acid during concentration and drying. However, this limitation is not found within the claims and it is improper to construe the claims by importing such limitations from the specification into the claims, see MPEP 2111.01 II.

In reply, Applicants respectfully note that this position seemingly overlooks the "wherein clause" in claim 31 requiring that "steps b) and c) are carried out in a spray drying procedure." This in turn requires that the crosslinking occurs during the concentration and spray drying stages. Thus, contrary to the position set forth in the Action, it is believed that the current claims do contain the argued limitation by requiring the crosslinking reaction to occur during concentrating a spray drying. Nonetheless, to further clarify the present invention, independent claim 31 has been amended to further specify that "the method is performed so as to crosslink the hyaluronic acid derivative during concentration and drying" as supported by the disclosure, for example, at paragraph [0056] on page 28 of the original specification, which corresponds to paragraph [0106] of US 2007/0134334 Al. Accordingly, the amended claims exclude the crosslinking reaction from occurring prior to steps (b) and (c). As such, claim 31, as amended, clearly differentiates from the disclosure of Yamamoto et al., Schense et al. and Shu et al.) for the same reasons noted above and in the last response. Again, none of the cited references disclose or suggest formation of crosslinkage during concentration and drying, as clearly recited in the claims.

For these reasons, Applicants respectfully submit the combination of Yamamoto et al., Schense et al., and Shu et al. fail to disclose or suggest each and every element of independent claim 31. Thus, claim 31 and all claims dependent thereon are believed to be novel and patentable over the combined cited references. Therefore, the above-noted obviousness rejection is untenable and should be withdrawn.

IV. Conclusion

Having addressed all the outstanding issues, this paper is believed to be fully responsive to the Office Action. It is respectfully submitted that the claims are in condition for allowance, and favorable action thereon is requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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